Details of CLIA Final QC Regulatory Changes

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Subpart A
General Provisions

- **NEW REQUIREMENTS**
  - Revised definitions for calibration, FDA-cleared or approved, reportable range & test system.
  - Replaced NIDA (National Institute for Drug Abuse) with SAMHSA (Substance Abuse & Mental Health Services Administration).

Subpart I
Proficiency Testing

- **P T REQUIREMENTS**
  - Changed 90% consensus to 80% consensus for referee lab grading by PT providers.
    - Reduces number of ungradables.
    - Permits labs to “get more for their money”.
    - Facilitates better lab education; i.e., error ID & correction.

Subpart J
Facility Administration

- **<u>FACILITY REQUIREMENTS</u>**
  - Apply to moderate & high labs (nonwaived).
  - Includes:
    - Mostly generally applicable requirements.
    - Coordination w/ Federal, State & local laws.
    - Transfusion/FDA-related information.
    - Safety provisions.
    - Record keeping standards;e.g., record retention.

Subpart J
Facility Administration

- **NEW FACILITY REQUIREMENTS:**
  - Comply w/ Federal, State & local laws.
  - Ensure adequate safety precautions to provide protection from lab hazards are accessible.
  - Contains molecular amplification procedures.
- **Record Retention**
  - Preserve records properly.
  - Requires record retention for closed facilities.
  - Retain test procedure 2 years after use.
  - Retain performance specifications 2 years.

Subpart J
Facility Administration

- **<u>Requirements for Transfusion Services</u>**
  - Report transfusion reactions/fatalities to lab & authorities.
  - Retain BB records same as FDA requires.

Subpart K
Quality Systems

- **QUALITY SYSTEMS REQUIREMENTS**
  - Applies to nonwaived (mod. & high) testing.
  - **General Laboratory**
    - Requirements for confidentiality, specimen integrity, complaints & communication.
  - **Pre-analytical**
  - **Analytical**
  - **Post analytical**
  - Parallels specimen flow through the lab.
  - Emphasizes Quality Assessment.

Subpart K
Quality Systems

- **COMPONENTS OF QUALITY SYSTEMS**
  - Calibration requirements.
  - Test verification standards.
  - Removal of FDA role in QC.
  - PT & test accuracy.
  - Test ordering, recording & reporting requirements.
  - Reagent storage & other QC standards.
  - Specialty/subspecialty QC, etc.

Subpart K Quality Systems

- **<u>Evaluation of PT Performance:</u>**
  - Verify accuracy of tests w/ no evaluation or score.
  - Verify accuracy of test when PT score doesn't reflect test performance.
  - Verify accuracy twice annually of regulated analytes for which compatible PT material isn't available from PT providers.

Subpart K
Quality Systems

- **PRE-ANALYTICAL**
  - Solicit patient's age, sex or DOB.
  - Solicit specimen source, when appropriate.

Subpart K
Quality Systems

- **ANALYTICAL**
  - Provides flexibility for calibrator selection.
  - Follow mfgr's. instructions for storage of reagents, specimens & test systems.
  - Removed FDA product dating info to guidelines.
  - Director must sign procedures & changes prior to use.
  - Follow manufacturer's instructions for maintenance & function checks.

Subpart K
Quality Systems

- **<u>Performance Specifications-test validation:</u>**
  - Applies to both moderate & high tests.
  - Perform only once for new tests!
  - Establish accuracy, precision, reportable range.
  - Verify manufacturer's normal values.
  - Determine calibration & calibration control procedures.

Subpart K
Quality Systems

- **Control Procedures**
  - Perform hematology QC once/day.
  - Utilize control system capable of detecting reaction inhibition for molecular amplification.
  - Include for electrophoretic procedures one QC material w/ substance being measured.
  - Use a different lot of calibrators as controls than those used to calibrate test.

Subpart K
Quality Systems

- **Microbiology**
  - Use a control organism with a negative acid fast reaction for mycobacteriology.
  - Check each batch, lot & shipment of lactophenol cotton blue only when prepared or opened for intended reactivity.
  - Test each batch of media & lot no.& shipment of antifungal agents before or concurrent w/ initial use.

Subpart K
Quality Systems

- **Immunohematology**
  - Included only specific cites for FDA BB (21 CFR) requirements under CLIA.
- **Histopathology**
  - Check immunohistochemical stains for pos. & neg. reactivity each time of use.
  - Provide neuromuscular pathology reports if trained in neuromuscular pathology.

Subpart K
Quality Systems

- **Cytogenetics**
  - Maintain records of resolution used as appropriate for type of tissue or specimen & study type.
  - Require full chromosome analysis for sex determination.
  - Utilize the International System of Cytogenetic Nomenclature on report.

Subpart K
Quality Systems

- **Histocompatibility**
  - Determine a technique that detects HLA specific antibody w/ a specificity equivalent or superior to that of the basic microlymphocytotoxicity assay.
    - Use a method that distinguishes HLA class antigens from antibodies to Class I antigens.
  - Have available monthly serum specimens for screening & crossmatch; follow policy consistent w/ clinical transplant protocols for frequency of antibody screening.

Subpart K
Quality Systems

- **Histocompatibility cont'd.**
  - Document techniques for increased sensitivity compared to basic complement-dependent microlymphocytoxicity assay.
  - Define test protocols for each type of cell, tissue or organ to be transfused or transplanted.
  - Follow policies that address when HLA testing & final crossmatches are required for pre-sensitized non-renal transplant recipients.

Subpart K
Quality Systems

- **<u>Histocompatibility cont'd.</u>**
  - Requires reagent specificity when reagent prepared in-house.
  - Establish technique to optimally define HLA Class I & II.

Subpart K
Quality Systems

- **<u>POST ANALYTICAL—Test Report</u>**
  - State date of test report on report & include specimen source, if applicable.
  - Include name & ID no. or unique patient identifier & ID no.

Subpart M Personnel

- **PERSONNEL REQUIREMENTS**
  - Represents only remaining complexity-dependent requirements.
  - Permits individuals w/ doctoral degree serving as high complexity directors before 2/24/03 to continue to qualify.
  - Prospectively requires board certification for **new** high **c**omplexity doctoral degreed directors**.**
  - Approved Boards to be listed in Appendix C of Surveyor Guidelines instead of regulations.

CLIA FINAL QC REGULATIONS

- **CONTACT INFORMATION:**
  - CMS WEB SITE: www.cms.hhs.gov/clia
  - CMS LAB DIVISION: 410-786-3531(phone)
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THE END

THANK YOU!!

QUESTIONS????